AMERICAN ACADEMY OF FAMILY PHYSICIANS

December 18, 2020

ADM Brett P. Giroir, M.D.
Assistant Secretary for Health
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 715-G
Washington, D.C. 20201

Re: Request for Information-Landscape Analysis to Leverage Novel Technologies for Chronic Disease Management for Aging Underserved Populations

Dear Admiral Giroir:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 136,700 family physicians and medical students across the country, I appreciate the opportunity to provide comments on the request for information (RFI) on leveraging novel technologies for chronic disease management in aging underserved populations, as published in the November 17, 2020 version of the *Federal Register*.

Family physicians provide comprehensive primary care services to patients across the lifespan, including for the aging population. Family physicians provide care management services to patients with chronic conditions, coordinating care across a team of clinicians and addressing social needs. The AAFP believes that artificial intelligence and machine learning (AI/ML) has great promise to transform the practice of medicine and improve outcomes for patients, which is why we created the AAFP Innovation Laboratory in 2019 to drive innovation using advanced technological platforms and tools, including AI/ML. The AAFP also partnered with the Center for Medicare and Medicaid Innovation to launch the Artificial Intelligence Health Outcomes Challenge.

While the AAFP is strongly supportive of efforts to harness AI/ML technology, we recognize the limitations and pitfalls of this technology. First and foremost, this new technology is incapable of replacing physicians' clinical judgement, shared decision making, or the patient-physician relationship and therefore should be designed to enhance care delivery and user experience in partnership with the user. Also critically important is ensuring that AI-based solutions do not exacerbate racial and other inequities that are pervasive our health care system. We strongly believe that systematic approaches must be implemented to evaluate the development and implementation of AI/ML solutions into health care. For example, we can look to the FDA Safety and Innovation Act (FDASIA) efforts to create a risk-based oversight framework to guide the development of a systematic approach. This will help balance innovation and patient safety as new AI/ML solutions are deployed in health care. The AAFP further believes it is critical to create an environment that enables clinicians and patients to trust AI-based solutions. Much of this trust will be fostered by using technology that requires partnership with either the physician or patient. With these goals in mind, we offer the following comments in response to your request for information.

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A. Barriers and Opportunities for Technology-Driven Solutions

1. What barriers (e.g., privacy concerns, other clinician and patient barriers) and opportunities are most relevant for bringing technology-driven solutions to aging populations in underserved areas?

One of the primary benefits of AI-based technology is the ability to leverage voice and natural language when users interact, limiting usability challenges that are often experienced with new technology. This is particularly beneficial in the elderly population. We believe that family physicians and other clinicians, who often report frustration with using electronic health records and other technology, may be more willing to use AI-based solutions due to the improved user experience.

While usability issues may be limited with AI technology, the lack of trust among both physicians and patients will be a significant hurdle to achieving meaningful implementation. Physicians, patients, and other health care stakeholders will be appropriately skeptical of an AI-based solution being involved with clinical decision making. These new solutions are not easy for users to evaluate for accuracy, lack of bias, and reliability. Further, recent studies indicate that clinical guidance and existing algorithms for clinical decision making may be based on biased studies and exacerbate inequities.[1] One study found that an algorithm used in hospitals systematically discriminated against Black patients.[2] Experts also predict that rapid implementation of AI-solutions amid the COVID-19 pandemic may widen the already disparate impact of the virus.[3] In order to improve trust in AI/ML solutions, these issues will need to be addressed head-on before AI-solutions can be successfully integrated into clinical care. It will also need to be made clear that AI-based technology is meant to augment decisions made by the user, not replace their clinical judgement or shared decision making. We provide additional recommendations for improving trust in question 7.

A related barrier is the quality of data that is used to train and develop AI solutions. It is critical for AI solutions to train on large volumes of high-quality data that are representative of the patients to which the AI solution will be applied. Improving the availability of such data may require reexamining current privacy regulations and furthers the need for national, wide-scale interoperability.

We believe the federal government should play a significant role in public-private collaborations that are led by physicians, patients, and other clinicians to address these barriers.

3. What new federal policies could facilitate the success of technology-driven solutions for aging populations?

Regulations governing health data privacy, payment, coverage, and liability will need to be modified to support the use of AI/ML solutions. Access to large volumes of high-quality data is needed to enable safe and effective AI solutions. The existing data privacy regulatory framework is not optimized to balance such access and individual privacy. Work will be needed to address this to accelerate the development of AI solutions.

AI solutions provide a new type of offering that has characteristics of both a diagnostic test and a consultation. Our current payment, coverage, and liability frameworks are not designed to accommodate this new hybrid offering. Federal policies that facilitate the use and affordability of AI/ML technology will be required in order to improve access and ensure that these new technologies do not exacerbate existing inequities.

7. How will healthcare team and patient trust in technology solutions be addressed? How will legal and ethical issues be addressed for technology solutions designed for improving chronic disease outcomes?

To foster trust in AI-based solutions, the AAFP recommends beginning with AI-based solutions that provide high-value support to the user in lower risk ways. For example, in piloting the use of AI/ML technologies in family medicine, the AAFP is first testing solutions that reduce administrative burden experienced by physicians and other clinicians. Administrative burden is a large contributor to physician burnout and dissatisfaction with practice. A recent study found that primary care physicians spend about half of their time on administrative tasks, which was more time than they spent on clinical activities.[4] While reducing administrative burdens is a high-value use for AI solutions, there are far fewer risks to patients or clinicians in the event that there is a problem with the AI technology if it is only supporting administrative functions. Using AI solutions to reduce administrative burdens allows physicians understand how AI solutions can work in the real-world and become comfortable with these new capabilities. Such high-value, low-risk opportunities should be identified as starting points for aging, underserved populations, as well as the family physicians and other clinicians that care for them.

Liability reform must be addressed in order to improve physicians' trust. Companies providing AI solutions must share the liability with physicians and other clinicians. We believe that the work on the FDAISA risk-based framework for oversight of CDS could be levered to establish a risk-based approach to determine the level of liability that should be shared between the AI company and the clinician.

<u>B. Key Indicators & Data Sources of Technology-Driven Chronic Disease Management</u>

1. What key indicators or data sets will be used to perform measure outcomes (e.g., racial, ethnic, gender, and socioeconomic disparities)?

AI solutions must be trained on large data sets that are representative of the patient populations they will be applied for. A myriad of health care stakeholders, including the federal government, will need to support the appropriate inclusion of data from patients of all racial, ethnic, gender, and socioeconomic types. AI solutions must report metrics about the patient characteristics that were included in the training data for the AI model. Physicians and other clinicians need these meta-data to understand if the AI model can be applied to their patients and how to interpret the AI's action or result.

It is extremely important that we do not allow the integration of AI technologies to further the biases already inherit in the health care system (and therefore in the data on to which AI is trained). If AI models are not trained on representative data, the value of the AI-based solutions will be limited to the populations that were included, exacerbating the digital divide, other inequities, and ongoing mistrust in the health care system. The AAFP strongly recommends that all stakeholders prioritize equitable implementation of new technologies.

<u>D. Public-Private Partnerships</u>

2. What organizations, groups, and/or, associations should HHS engage as part of such a collaborative effort? HHS encourages all potentially interested parties—individuals, associations, governmental, nongovernmental organizations, academic institutions, and private sector entities—to respond.

We believe that it is critical that such a collaborative effort be led by physicians, patients, and other clinicians. This will ensure user-centered design of AI solutions and will help establish the needed trust to accelerate the safe adoption of these solutions. Of course, all stakeholders should be part of the collaborative, including federal and state government, academic institutions, AI developers, and consumer technology vendors.

Thank for the opportunity to provide comments on the RFI. Should you have any questions, please contact Meredith Yinger, Senior Regulatory Strategist, at myinger@aafp.org or 202-235-5126.

Sincerely,

Gary L. LeRoy, MD, FAAFP

Gary LeRoy, MD, FAAFP
Board Chair
American Academy of Family Physicians

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